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Case No: HC12C00361

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 18/07/2014

Before :

MR JUSTICE WARREN

Between :

ELI LILLY AND COMPANY	**Claimant**
- and -	
HUMAN GENOME SCIENCES INC.	**Defendant**

Andrew Waugh QC and Tom Mitcheson QC (instructed by **Field Fisher Waterhouse LLP**) for the **Claimant**
Michael Tappin QC (instructed by **Powell Gilbert LLP**) for the **Defendant**

Hearing dates: 9th May and 4th June 2014

Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

.....

MR JUSTICE WARREN

Mr Justice Warren :

Introduction

1. This matter comes back before me following the decision ("**the Judgment**") of what I shall refer to in this judgment as "**the Court**" on the reference made by me in October 2012. This judgment should be read together with my earlier judgments on 3 August 2012 (see [2012] EWHC 2290 (Pat)) and 10 October 2012 (see [2012] EWHC 2857 (Pat)). I adopt the definitions found in those judgments (which I will refer to as my first and second judgments).

2. The Court, as is often the case, reformulated the three questions which I had referred into a single question

> "whether Article 3(a) of Regulation No 469/2009 [the SPC Regulation] must be interpreted as meaning that, in order for an active ingredient to be regarded as 'protected by a basic patent in force', within the meaning of that provision, the active ingredient must be identified in the claims of the patent by a structural formula, or whether the active ingredient may also be considered to be protected where it is covered by a functional formula in the patent claims."

3. The Court answered its own question in the following way. Article 3(a) of the SPC Regulation must be interpreted as meaning

> "that, in order for an active ingredient to be regarded as 'protected by a basic patent in force' within the meaning of that provision, it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula. Where the active ingredient is covered by a functional formula in the claims of a patent issued by the European Patent Office, Article 3(a) of [the SPC Regulation] does not, in principle, preclude the grant of a supplementary protection certificate for that active ingredient, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the Convention on the Grant of European Patents and the Protocol on the interpretation of that provision, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, which is a matter to be determined by the referring court"

4. As will become apparent, one thing the Judgment does not give is the clear guidance which the reference was designed to obtain. Whilst each side can reasonably find support for their preferred outcome from what the Court says in different parts of the Judgment, some of the language used in the submissions to the effect that the Judgment is absolutely clear (in one direction or the other) – or as Walton J was fond of saying, plain as a pikestaff – is, unfortunately for me and the parties, rather wide of the mark.

Statutory and legal background

5. In order to deal with and understand the arguments presented to me, and in order to attempt to understand what the answer given by the Court means, it is helpful to consider some of the statutory provisions and some of the case law which form part of the matrix within which the meaning and effect of the Judgment is to be ascertained. I summarised the relevant provisions of the SPC Regulation in [22] of my judgment dated 3 August 2012 and do not repeat it here other than to remind myself that:

   i) Article 3(a) states, as one condition for the grant of an SPC, that "the product is protected by a basic patent in force"; and

   ii) "product" is defined in Article 3(b) as "the active ingredient or combination of active ingredients of a medicinal product" and "basic patent" is defined in Article 1(c) as "a patent which protects a product as such, a process to obtain such a product or an application of a product ... ".

6. So to obtain an SPC what is required, among other things, is a basic patent. The patent can be for a product or for a process to make a product or for an application of a product. The basic patent does not need to have anything about it which is to do with the use of a product.

7. In the light of the argument now advanced, I also set out recitals (4) and (5) to the SPC Regulation:

> "(4) At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into such research.
>
> (5) This situation leads to a lack of protection which penalises pharmaceutical research."

8. Article 69(1) of the European Patent Convention ("**the EPC**") deals with "extent of protection" as follows:

> "The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims."

9. The Protocol on Interpretation of Article 69 provides, on the one hand, that Article 69 "should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims". But on the other hand "Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated". The Protocol provides for a balance to be struck: "On the contrary, it is to be interpreted as defining a position

between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties".

10. The provisions are transposed into domestic law by section 125(1) read with sections 125(3) and 130(7). It is worth reminding oneself of what section 125(1) actually says, well-known as it will be to most readers of this judgment:

> "For the purposes of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly."

11. As to the cases (and the Judgment itself), it is important not to lose sight of the fact that we are dealing with a piece of legislation which provides for the granting of an SPC where the product is protected by a basic patent. The issue is what "protected" means. It is in that context that I am concerned with the meaning of the words "specified" and "identified" used by the Court in various judgments when giving guidance to the national court in deciding what is protected.

12. I can start with Case C-322/10 *Medeva BV v Comptroller General of Patents, Designs and Trade Marks ("**Medeva**")* on which both sides rely. It has been referred to in a number of subsequent cases to some of which I will come in due course. The patent claim concerned is set out at [11] of the Opinion of the Advocate General. It is a claim to a method of preparing an acellular vaccine. One point to note is that although the word "comprises" is used, that is in relation to the method; there is nothing here (or anywhere else in the patent) about including any active ingredient in the vaccine other than those mentioned in the claim.

13. Mr Tappin, who appears for HCS, has helpfully summarised the facts of *Medeva* in this way:

i) Medeva had a patent for a method of making a whooping cough vaccine consisting of a combination of two antigens (we can call them A and B) as active ingredients. It filed a number of applications for SPCs in respect of combination vaccines. The applications fell into two categories but for present purposes it is the first category which matters. That category consisted of applications for SPCs in respect of combinations of active ingredients which included extra active ingredients, in addition to A and B. Those extra active ingredients (we can call them X, Y and Z) had nothing to do with the patent or its claims.

ii) The UK IPO refused to grant that first category of SPCs, saying that they did not satisfy Article 3(a). The Court of Appeal referred questions to the Court asking whether Article 3(a) prevented an SPC from being granted in respect of a combination of active ingredients which included active ingredients not mentioned in the claims of the basic patent.

iii) Medeva's case, as recorded in [20] of the judgment of the Court, was that the concept of a 'product ... protected by a basic patent in force' within the meaning of Article 3(a) included any combination of substances of a medicinal product which directly infringed the patent. In other words, a product consisting of active ingredients A, B, X, Y and Z was "protected by" its patent because selling that product would infringe the patent – the so-called "infringement test". That case was rejected by the Court.

14. Mr Tappin spent some time in his written and oral submissions looking at what Advocate General Trstenjak had said in her opinion, referring in particular to her conclusion in relation to Article 3(a) in [112]-[113]. She referred to the "subject-matter" of a basic patent, explaining what she meant by that in [68] to [70]. She took the view that whether a product forms the subject-matter of a basic patent within the meaning of Article 1(c) was determined, in principle, according to the rules governing the basic patent. She drew a distinction between the subject matter (or, using her alternative description, its "extent of protection") of the basic patent and what she referred to as its protective effect. As the Court of Appeal recognised in its judgment following the reference (see *Medeva BV v Comptroller General of Patents, Designs and Trade Marks* [2012] EWCA Civ 523 at [31]), she equated "subject-matter" with "extent of protection".

15. It is unfortunate, perhaps, that she used the words "extent of protection" because she herself contrasted the subject matter or extent of protection with the protective effect: there is clearly room here for confusion over the meaning of protect/protective. But what she meant by protective effect (in contrast with extent of protection) in [68] to [70] was surely the bundle of rights and remedies which the basic patent afforded which would subsume the remedies for infringement of the patent.

16. On the facts of *Medeva*, her approach was reasonably straightforward in its application. She drew a distinction between a case in which the only active ingredient in the product forms (or all the active ingredients in a combination product form) part of the subject-matter of the claims; and a case where the patent would prevent someone selling the product in question, being a combination of active ingredients, because the combination product *included* an active ingredient (or active ingredients) which was (or were) part of the subject-matter of the claims, but the combination product also contained other active ingredients which were not part of the subject-matter of the claims. On any view of subject matter in contrast with protective effect, antigens A and B formed the subject matter of the basic patent whereas ingredients X, Y and Z did not. And on any view, antigens A and B were protected by the basic patent within the meaning of Article 3(a).

17. The Court did not refer to the Advocate General's opinion nor did it adopt her reasoning, although it is the case that the Court's decision and reasoning is consistent with her opinion. The Court took matters shortly, expressing itself succinctly in [25] and [26] of the Judgment:

> "25. Moreover, it should be recalled that Article 5 of Regulation No 469/2009 provides that any SPC confers the same rights as conferred by the basic patent and is subject to the same limitations and the same obligations. It follows that Article 3(a) of the regulation precludes the grant of a SPC

> relating to active ingredients which are not specified in the wording of the claims of the basic patent.
>
> 26. Similarly, if a patent claims that a product is composed of two active ingredients but does not make any claim in relation to one of those active ingredients individually, a SPC cannot be granted on the basis of such a patent for the one active ingredient considered in isolation."

18. The first sentence of [25] sets the context for the second sentence. The conclusion concerning the need for the active ingredients to be specified in the wording of the claims of the basic patent is said to follow from the fact that the SPC confers the same rights as the basic patent. The reasoning here must be that the SPC is not to confer more extensive rights than the basic patent. If a product is "specified" (whatever that may mean) in the basic patent, then the SPC will not confer more extensive rights than the basic patent. The logic of this reasoning has to be that if a product is not "specified" in the basic patent, then an SPC cannot be granted because that would result in more extensive rights being conferred by virtue of the SPC than under the patent. However, that will not be so if "specified" is given too restricted a meaning: a product might then fall within the claims of a patent without thereby being "specified" and yet an SPC granted in relation to the product would confer no greater rights than the basic patent. This is not to say that "specified" is not to be interpreted in the way that Lilly submits, since it may be wrong to read this strict logic into what the Court said. But what can, I think, be said is that Article 5 does not lead to the conclusion which the Court reached.

19. As to [26], the starting point is that the basic patent does not make any claim in relation to one of the active ingredients individually. If it were possible to obtain an SPC in relation to that ingredient, then the SPC would confer rights which were more extensive, in relation to that ingredient, than those conferred by the basic patent. Article 5 would not be respected.

20. The word "specified" is the word found in section 125. In subsequent reasoned orders, the Court used the word "identified" rather than "specified" but there is nothing to suggest that it thereby intended to say anything different. The references here are to Case C-518/10 *Yeda Research and Development,* Case C-630/10 *University of Queensland and CSL* [2011] ECR I-12231, and Case C-6/11 *Daiichi Sankyo* [2011] ECR I-12255.

21. The case law prior to the reference in the present case has been considered by Arnold J in two decisions: *Novartis v Medimmune* [2012] EWHC 181 (Pat) and *Actavis v Sanofi* [2012] EWHC 2545 (Pat) (in which he himself made the reference referred to in my second judgment in the present proceedings). In eschewing repetition of Arnold J's analysis of the cases, I shall emulate Mr Waugh and Mr Mitcheson, who appear for Eli Lilley, and who in their skeleton argument, said this:

> "Given Arnold J.'s succinct yet comprehensive analysis we do not repeat it here but commend the judgment at paras. 14 - 49, both for the review of the above cases and for the background to *Medeva* and its progeny."

Like them, I commend those paragraphs to the reader of this judgment.

22. In *Novartis,* Arnold J expressed his disappointment that the Court had not answered question 1 of the reference made in *Medeva.* He identified several different ways in which the absence of hoped-for guidance had left so many issues unclear leading to the conclusion that "Regrettably, therefore, it is inevitable that there will have to be further references to the CJEU to obtain clarification of the test".

23. In *Actavis,* Arnold J brought his analysis up to date when making another reference to the Court, repeating in measured language his disappointment. He referred to the judgment of the Chancellor, Sir Andrew Morritt, in the Court of Appeal when *Medeva* returned to it (again, see the reference above) and to my first judgment, noting that the Court of Appeal agreed that the test laid down by the Court in *Medeva* and its progeny is unclear save in its rejection of the infringement test in combination cases and that further references are required to obtain clarification of the test.

24. At this point, I turn to the judgment of the Chancellor in *Medeva*, which I have just mentioned. For present purposes, I need refer only to [31] to [34]. In [31], the Chancellor identified the choice as being between "what is easily recognised as the infringement test and what the Advocate General [in *Medeva*] described as "the subject matter of the patent" but may also be labelled "the scope of protection" test". In [32], he considered that it was clear that the Advocate General had rejected the infringement test; and whilst recognising that the judgment of the Court was not so clear, he considered that the language of the Court was inconsistent with any implication that the protective effect of the patent had any relevance to the issue before the Court.

25. The Chancellor then went on at [33] to say this:

> "Thus the issue for the national court is to determine which active ingredients are specified in the wording of the claims. The ambit of "specified" may range from express naming, through description, necessary implication to reasonable interpretation. Where on that scale the dividing line is to be drawn will necessitate further references in due course in the light of the facts of the cases in which the issue arises. The problem for Medeva in this case is that wherever the dividing line is to be drawn the active ingredients relating to vaccines against diphtheria, tetanus, meningitis and polio are excluded."

26. Then, in [34], he rejected the suggestion that those ingredients might be included on the basis of the rule or convention that in drafting patent specifications the word "comprising" does not exclude other elements:

> "The ruling of the Court of Justice requires that the other elements or active ingredients are specified in the wording of the claims. There must be some wording indicating that they are included in the claims. Were it otherwise the Court of Justice would be imposing the infringement test which the Advocate General expressly and the Court of Justice by necessary implication had excluded."

27. The Chancellor here appears to equate the requirement that the other elements are specified in the claims with the need to have "some wording indicating that they are included in the claims". That approach is, I think, another helpful way of articulating the concept which both the Advocate General and the Court in *Medeva* were seeking to capture.

28. Before turning to the Judgment itself, I mention the litigation between the parties relating to the validity of the Patent. It was described in [8] to [11] of my first judgment as matters then stood and updated in [6] and [7] of my second judgment. There being no further appeal to the Supreme Court, the position is that the Patent has been held to be valid by the UK courts, as it has been by the Technical Board of Appeal. HGS faced a large number of attacks on validity. The Supreme Court has held, however, that the claims are capable of industrial application. As Lewison LJ put it at [58] of his judgment when the matter came back to the Court of Appeal to resolve the outstanding matters (see [2012] EWCA Civ 1185), the Supreme Court has answered the question: what is it for and what are the chances that it will work?, going on in [60]*ff* to what "it" is that the patent must teach. He rejected (as did Sir Robin Jacob) Mr Waugh's submission that claim 13 was a claim to *'useful'* antibodies. He rejected the submission that, if you claim a broad class which includes a functional characteristic the invention is only sufficiently described if a skilled person can reasonably expect that substantially all members of the class can be made and put into practice on the basis of what the patent teaches, combined with common general knowledge. He also rejected the submission that claims 18 and 19 claimed a medical use, holding at [73] that they claimed products. At [73], he says this:

> ".... There is no difficulty in making the products. The difficulty is in knowing which of the products would be worthwhile introducing into a human or animal body; and in what circumstances. But that, as I see it, is part of the question: is there a good enough chance that it will work? That question has been answered affirmatively by the Supreme Court..... This construction gains added force from a reading of the specification as a whole. It is clear from the specification that the patentee had no real idea what neutrokine-α or its antibodies would do if introduced into a living creature..... "

29. Sir Robin Jacob made the same point in different language at [51] and [52]:

> "51. [Mr Thorley] submitted that read in the context of the specification as a whole, the skilled reader would not expect the patentee to have intended these claims to be directed to compositions with immediate practical use as a pharmaceutical or diagnostic. On the contrary he would know that no such compositions had been disclosed and that what the patentee had discovered and disclosed is neutrokine-α and its antibodies with a practical use for these purposes yet to be discovered. So there is no reason to suppose that in these claims the patentee intended any specific application for the claimed compositions. They are not tied to any particular application. It follows that all he must have meant is compositions which could be

> formulated as suitable for administration as a pharmaceutical or suitable for use as a diagnostic. That could be done and so the claims are sufficient.
>
> I accept that submission. It is in accordance with the principles of construction laid down in *Kirin-Amgen* [2005] RPC 9. The contrary view is not, involving as it does the skilled reader in ignoring the very general high level nature of this invention."

The Patent

30. The relevant claims are set out at [13] of the Judgment. They are as follows:

> "13. An isolated antibody or portion thereof that binds specifically to:
>
> (a) the full length Neutrokine-α polypeptide (amino acid sequence of residues 1 to 285 of SEQ ID NO:2); or
>
> (b) the extracellular domain of the Neutrokine-α polypeptide (amino acid sequence of residues 73 to 285 of SEQ ID NO:2)
>
> 14. The antibody or portion thereof of claim 13 which is selected from the group consisting of
>
> (a) a monoclonal antibody;
>
> ... .
>
> 18. A pharmaceutical composition .... comprising the antibody or portion thereof of any one of claims 13 to 17 and, optionally, a pharmaceutically acceptable carrier."

31. In spite of the time spent by Mr Waugh in his oral opening taking me through some of the science, I do not think I need to say much about it in this judgment. Once a novel target protein has been identified, (in our case Neutrokine-α) it is possible to use standard techniques to produce antibodies to it. The Patent has been held to be sufficient across the scope of claim 13: it amounts to an enabling disclosure of all the antibodies claimed. In their skeleton argument, Mr Waugh and Mr Mitcheson produce a schematic representation of an antibody, or immunoglobulin, where there are two light chains and two heavy chains joined together. As Mr Tappin succinctly describes it, this is a particular chemical made up of a large number of amino acid residues and, at various points, there may be carbohydrate chains attached to the sides of the amino acid chains.

32. Each light and heavy chain has a variable region. Each of these variable regions has, in this particular schematic representation, three hypervariable regions also known as complementarity determining regions or CDRs. The CDRs are the amino acid residues which contact the antigen and each antibody will have a particular set of amino acid residues in its CDRs; but there will be a wide variety of possible CDR

sequences which combine to any target protein. The CDRs are only a small part of the total antibody sequence. And so, Mr Tappin correctly observes that merely writing down the amino acid sequences of the CDRs does not amount to a description of an individual antibody. It is also to be noted that regulatory approval is not given for "an antibody with this set of CDRs", rather, approval is given for a particular antibody molecule.

33. Mr Tappin explained that CDRs are not the only part of an antibody sequence which is of importance in relation to the antibody and its antigen binding properties. The CDRs sit in the variable region in what is called the framework. Each variable region has frameworks which surround the CDRs: they are amino acid residues in the same way as the CDRs themselves. The interactions between framework residues and CDRs can dramatically and unpredictably affect the characteristics of antibodies. It is sometimes possible to improve the properties of an antibody by making alterations to the framework residues. By doing so, the affinity, the strength with which the CDRs bind to an antigen, can be affected. None of this was challenged by Mr Waugh.

34. What this illustrates is that there are several stages of research which may go into the development of an antibody for practical use. Thus, there can be the initial identification of a new target protein which enables production of antibodies which bind to that target. An antibody perceived to have potential for use may be identified; and then modifications made to the framework or elsewhere in the molecule may be made to make it more effective. Before actual medical use can be made of the molecule, clinical trials are necessary. Those trials, in particular the Phase III clinical trials, are expensive. Of course, it is not necessary to get to that stage of development before a patent can be granted.

35. Claim 13 claims all antibodies which bind to Neutrokine-α. Mr Tappin acknowledges that this will amount to many, many thousands of antibodies. It includes HGS's antibody belimumab (also known as Benlysta) as well as Lilly's antibody tabalumab.

The Judgment

36. Against all of that background, I come to the Judgment. At [14], the Court refers to tabalumab, noting that Lilly recognised that, if marketed, that composition would infringe claim 13. The Court at [15] then notes my conclusion (which I repeat and from which the Court does not dissent) that tabalumab is an antibody as defined in claim 13, namely an isolated antibody or portion thereof that binds specifically to Neutrokine-α polypeptide. To use a word which the Court used later in the Judgment and in its ruling, tabalumab is "covered" by claim 13. In contrast, in *Medeva*, the product would have infringed the relevant patent but it was not covered by it in that sense. [21] records the argument that the patent uses standard forms of claim that are routinely granted by the EPO in cases involving patents for new proteins and antibodies that bind to them. It is standard practice that antibodies binding to previously unidentified proteins are considered novel and inventive. That, it is argued, justifies "broad antibody *per se* protection being obtained where the basic patent contains claims which expressly refer to 'an antibody capable of binding to the [novel protein]'"; claims, such as claim 13, provide an appropriate and justified level of protection for the invention even though they cover multiple antibodies. And so, the argument runs, it is recognised by European patent law that it is neither

appropriate nor necessary to require such inventions to provide a more specific, structural definition of the antibodies in their claims.

37. The Court's consideration of the arguments starts at [24] of the Judgment. In [24] the Court reformulates the questions referred as I have already described; and in [25] it (correctly) notes that the referring court is uncertain whether the criteria for determining whether a product is protected by a basic patent in force within Article 3(a) are different where the product is a single active ingredient as opposed to a combination of active ingredients.

38. At [26], the Court says this:

> "26 Whereas HGS maintains that a product may be regarded as being identified in the claims of a basic patent and thus protected by the patent where the product is identified by means of a functional formula or definition, including an indication that it forms part of a specific therapeutic class, Eli Lilly is of the view that, in order to enjoy such protection, the active ingredient must be adequately identified and described in the descriptions and claims of the basic patent, which is not the case in the main proceedings. Accordingly, Eli Lilly submits that, in this case, in the light of Article 3(a) of Regulation No 469/2009, the active ingredient tabalumab, which it has developed, is neither identified nor 'protected' by HGS's patent, in spite of the fact that, during the lifetime of that patent, it cannot place that active ingredient on the market without infringing HGS's patent."

39. In [30] – [35] of the Judgment, the Court draws attention to the function of the claims. In [30], the lack of harmonisation in relation to patents is noted, with reference being made to [22] of *Medeva* (where reference is made to *Farmitalia*). It is then observed, at [31] that, since there are no harmonised patent rules, the extent of the protection conferred by a basic patent can be determined only in the light of the non-European Union rules governing patents. Those rules are more specifically identified in [32] and [33]:

> "32. It must be borne in mind that the rules for determining what is protected by a basic patent for the purpose of Article 3(a) of Regulation No 469/2009 are those relating to the extent of the invention covered by such a patent, such as the rules laid down in the main proceedings in section 125 of the UK Patents Act 1977. Where the patent in question has been granted by the EPO, those rules are also the rules laid down in the EPC and Protocol on the Interpretation of Article 69 of that convention.
>
> 33. On the other hand, as is apparent from the response given by the Court to questions 1 to 5 in the case which gave rise to the judgment in *Medeva*, for the purpose of determining whether a product is 'protected by a basic patent in force' within the meaning of Article 3(a) of Regulation No 469/2009, recourse may not be had to the rules governing infringement

> proceedings, such as, in the main proceedings, those laid down in section 60 of the UK Patents Act 1977."

40. Reading these paragraphs of the Judgment in isolation, it might be thought that [33] is simply affirmation of the rejection in *Medeva* of the infringement test and that [32] is doing no more than equate the protection of a basic patent in force for the purposes of Article 3(a) with the relevant national law for ascertaining the extent of the invention. In a UK context, this would mean that a product is protected by a basic patent in force for the purposes of Article 3(a) if "but only if" the product is specified in a claim of the specification interpreted in accordance with section 125(1) (for which purpose, by virtue of section 125(3), the Protocol on the Interpretation of Article 69 of the European Patent Convention applies). Mr Tappin submits that this is, indeed, what the Court was saying in the Judgment. But Mr Waugh, submits that this cannot be what the Court meant. If that is what it did mean, he suggests that the Judgment would have looked very different. First, the Court would have made plain that that was what it was saying; and secondly, it would have produced a much shorter Judgment and would not need to have addressed matters which it did address.

41. Those paragraphs are not, however, to be read in isolation. They must be read in the context of the Judgment as a whole; and they must be read in the context of the other case law which I have already mentioned. It is, I think, best to set out most of the remainder of the Judgment, namely [34] and [36] to [43]:

> "34 By finding that Article 3(a) of Regulation No 469/2009 precludes the grant of an SPC relating to active ingredients which are not specified in the claims of a basic patent (see *Medeva*, paragraph 25, and the orders in Case C-630/10 *University of Queensland and CSL* [2011] WECR I-12231, paragraph 31, and Case C-6/11 *Daiichi Sankyo* [2011] ECR I-12255, paragraph 30), the Court emphasised the key role played by the claims for the purposes of determining whether a product is protected by a basic patent within the meaning of that provision."
>
> "36 In the main proceedings, it is common ground that the active ingredient tabalumab, namely LY2127399, is not expressly named in the claims of HGS's patent. Moreover, it would appear that it is not otherwise specified in the descriptions or specifications of that patent and cannot, therefore, be identified as such.
>
> 37 With regard to the fact that the marketing of that active ingredient by Eli Lilly during the lifetime of HGS's patent would constitute an infringement of the patent, it is clear, in the light of what has been stated at paragraphs 32 and 33 above, that that is not a crucial factor, for the purpose of granting an SPC on the basis of Regulation No 469/2009, in particular Article 3(a) of that regulation, in the determination of whether that active ingredient is protected by that patent.

38 It should be recalled that, in accordance with the case-law cited at paragraph 34 above, an active ingredient which is not identified in the claims of a basic patent by means of a structural, or indeed a functional definition cannot, in any event, be considered to be protected within the meaning of Article 3(a) of Regulation No 469/2009.

39 With regard to the question whether the use of a functional definition may alone be sufficient, it should be noted that Article 3(a) of Regulation No 469/2009 does not, in principle, preclude an active ingredient which is given a functional definition in the claims of a patent issued by the EPO being regarded as protected by the patent, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the EPC and Protocol on the interpretation of that provision, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question.

40 With regard to the requirements laid down by the EPC, it should, however, be noted that the Court does not have jurisdiction to interpret the provisions of that convention, since, unlike the Member States, the European Union has not acceded to the convention. The Court cannot, therefore, provide further guidance to the referring court concerning the manner in which it is determine the extent of the claims of a patent issued by the EPO.

41 Moreover, it should be recalled that the SPC is designed simply to re-establish a sufficient period of effective protection of the basic patent by permitting the holder to enjoy an additional period of exclusivity on the expiry of that patent, which is intended to compensate, at least in part, for the delay to the commercial exploitation of his invention by reason of the time which has elapsed between the date on which the application for the patent was filed and the date on which the first MA in the European Union was granted (Case C-229/09 *Hogan Lovells International* [2010] ECR I-11335, paragraph 50; Case C-443/12 *Actavis Group PTC and Actavis UK* [2013] ECR I-0000, paragraph 31; and Case C-484/12 *Georgetown University* [2013] ECR I-0000, paragraph 36).

42 As stated in recital 4 in the preamble to Regulation No 469/2009, the purpose of that additional period of exclusivity is to encourage research and, to that end, it is designed to ensure that the investments put into such research are covered.

43 In the light of the objective of Regulation No 469/2009, the refusal of an SPC application for an active ingredient which

> is not specifically referred to by a patent issued by the EPO relied on in support of such an application may be justified – in circumstances such as those in the main proceedings and as observed by Eli Lilly – where the holder of the patent in question has failed to take any steps to carry out more in-depth research and identify his invention specifically, making it possible to ascertain clearly the active ingredient which may be commercially exploited in a medicinal product corresponding to the needs of certain patients. In such a situation, if an SPC were granted to the patent holder, even though – since he was not the holder of the MA granted for the medicinal product developed from the specifications of the source patent – that patent holder had not made any investment in research relating to that aspect of his original invention, that would undermine the objective of Regulation No 469/2009, as referred to in recital 4 in the preamble thereto."

42. The Court, it can be seen, rejected the submissions which Lilly had made that a structural definition was necessary and that, as a minimum, it would normally require the amino acid sequences of the CDRs of its binding domains.

Argument and discussion

43. I wish to say at the outset of the discussion that I agree broadly with Mr Tappin's submissions. I will explain how I consider the Judgment is to be interpreted, drawing on many of his arguments. After that, I will turn to Mr Waugh's arguments, insofar as I have not dealt with them as I go along.

44. I start with the later part of the Judgment, from [41] to [43], where the Court is discussing the purpose of the SPC Regulation and the impact which that has on its interpretation. [41] gives rise to no particular problems.

45. I should, however, make some observations about what research is being referred to in [42] in the context of recital 4 to the SPC Regulation. There is, in my view, nothing in recital 4 which circumscribes the type of research or the period during which it takes place. The SPC Regulation does not discriminate between different stages or forms of research. As it is put in paragraph 29 of the Explanatory Memorandum underlying the SPC Regulation:

> "The purpose of the expression "product protected by a patent" is to specify what types of invention may serve as a basis for a certificate.
>
> The proposal does not provide for any exclusions. In other words, all pharmaceutical research, provided that it leads to a new invention that can be patented ... must be encouraged, without any discrimination..."

46. Some assistance can be derived from the opinion of Advocate General Fennelly in Case C-181/95 *Biogen Inc v SKB Biologicals SA*, quoted in [50] of my judgment of 3 August 2012:

> "Fourthly, there is nothing to support the defendant's contention that the Regulation was designed primarily to reward the expense and effort involved in developing marketable medicinal products, rather than pharmaceutical research in general, the results of which may require further development before marketing. While it is essential under the scheme of the Regulation that research ultimately results in a marketable medicinal product, the recitals in the preamble to the Regulation (such as the first, second and fourth) speak of pharmaceutical research in general, while Article 1(c) of the Regulation suggests that any patent, including one based on the most elementary research, may be designated as a basic patent for the purposes of applying for a certificate."

47. I do not read the Court as intending to qualify that approach in any way by what it said in [43] of the Judgment. An approach which discriminated between different stages of the research leading to an MA would be almost impossible of practical implementation. It would require a detailed enquiry about the extent to which work done at an early stage had value in the research done at a later stage which cannot have been the intention of the drafters of the SPC Regulation.

48. Further, an approach to Article 3(a) which produces different results depending on who carries out the later research – the original patentee or a third party – cannot be right in principle. Either a basic patent does, or does not, protect a product and I can see no ground at all for saying that the answer to that question depends on who produces the product. Indeed, it is to be noted that the answer given by the Court to the (reformulated) question referred does not depend on who invested in what research. It is no answer to this point to say, in a case where the original patentee brings his invention to the market with an appropriate MA, that it can obtain a further patent on a more closely defined invention on the way and then obtain an SPC on the basis of the further patent. There may be examples where the patentee would be able to obtain a further patent; but equally there will be cases where it could not do so and would need to rely on its original basic patent to obtain an SPC. The reasoning in [43] then has no application. I do not understand, therefore, how the question of who has spent money on research provides any indication, one way or the other, about what is "specified" or "identified" within the meaning of *Medeva* and subsequent cases.

49. What the Court said in [43] appears to me to be more apposite to the Third Party Issue and the Court may have had that in mind in saying what it did. The Third Party Issue featured in the submissions which the parties had made and may have coloured the Court's reasoning to some extent. If the Court was saying that a patentee, who had done nothing since obtaining his patent to ascertain the active ingredient which may be commercially exploited, should not be able to obtain an SPC, that would be because of policy considerations concerning <u>who</u> could obtain an SPC rather than <u>the circumstances in which</u> it could be obtained (*ie* whether the product is protected by basic patent). But that goes to the Third Party Issue which had been abandoned by the time of the hearing.

50. Further, in [43], the Court appears to have assumed that <u>because</u> the patent holder was not the holder of the MA, he would not have made any investment in the in-depth

research referred to. That assumption may, on the facts of any particular case, be wrong. It needs a factual enquiry to ascertain whether it is correct. Indeed, in the present case, HGS maintains that Lilly placed reliance on work which had been carried out by HGS including, among other things, sequence information which HGS had discovered and published. I was also asked to read some confidential material concerning trials to show that Lilly relied on HGS's work in developing tabalumab. These are factual matters over which the Court had no jurisdiction. It was not, therefore, for the Court to state ("in circumstances such as those in the main proceedings") as if it were an established fact that HGS had failed to take any steps to carry out more in-depth research and to identify "[its] invention specifically".

51. In any case, HGS did carry out more in-depth research to identify a commercial product, resulting in an MA for Benlysta. Clearly, the research which led to the Patent was important in ultimately achieving that MA. Once the Third Party Issue is put aside – abandoned – I see no reason why that earlier research is not equally important to, and as deserving of protection by reference to any other product, such as tabalumab, whoever is responsible for the development of that product. There is also this consideration. Suppose that HGS itself had been working on a research project which had identified the antibody now called tabalumab but was not at such an advanced stage of research as Lilly, with Lilly in a position to apply for an MA but with HGS nowhere near that position. It is difficult to see any policy objective, once the Third Party Issue is out of the way, which would lead to HGS being precluded from obtaining an SPC simply because it was Lilly which was in front in that particular race.

52. Moreover, there is one serious and unsatisfactory consequence of an approach which attaches any significance, in the context of Article 3(a), to who has paid for what research. Lilly's position is that an SPC cannot be based on the Patent even though it provides an enabling disclosure of the novel target protein, and antibodies to that target. The kind of fundamental research which opens up a new field in this way, identifying a new target and a range of antibodies, cannot Lilly say be rewarded with an SPC however ground-breaking the research may be. In the real word, subsequent research is often carried out by a third party, either with the licence of the original patent holder or, as in the present case, without such a licence. Lilly's case means that, if the subsequent research leads to a further patent, that patent can form the basis of an SPC but the initial patent cannot. A preference would therefore be given to those with a patent covering the second or third stages of a research programme for instance identifying a set of CDRs or making further modification to the sequence of other parts of the molecule. Mr Tappin submits that that would be contrary to the objectives of the SPC Regulation, one objective being to ensure that there is no discrimination between different types of patentable research. I agree.

53. Mr Tappin has also referred me to Case C-229/09 *Hogan Lovells International LLP v Bayer Crop Science AG* at [32] to demonstrate that the Regulation is to be interpreted "in the light of the overall scheme and objectives of the system of which it is a part". He submits that any suggestion that in [43] the CJEU is saying that HGS' research which led to the Patent is not of a type which can attract an SPC, would be inconsistent with that approach to interpretation and is to be rejected. Further, he says that it would be illogical to conclude that fundamental research which merited the grant of a patent and opened up the field, enabling the production of all specific

antibodies to a new target protein (as the UK courts and the TBA have held) did not merit supplementary protection because it was somehow too fundamental to count. I agree with all of this.

54. It is also to be noted that the Court reaches its conclusion about the sufficiency of a functional definition in [39], where it also states the condition that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question. What it says in that paragraph is restated in its final answer given in [44] and in its ruling. The Court cannot, surely, be intending in [43] to qualify the conclusion which it reaches in [39]. Nor can it be intending to qualify what it says in [32] that it is Article 69 (or section 125) which provides the rules for determining whether something is "protected by a basic patent" for the purposes of Article 3(a). Nor can this be intended to be guidance as to how the national court should apply Article 69, given what is said in [40].

55. I now turn to the earlier parts of the Judgment; these must be read in the light of the case law which I have mentioned, in particular *Medeva*. In that case, one sees the Court beginning to grapple, if I may use that word, with a concept which is not easy to articulate once one moves away from the clear, conceptually if not practically, infringement test. It is an elusive concept. Mr Tappin suggests that the Court was in essence attempting to discover what a patent is and is not "really about". Where a patent expressly identifies an active ingredient, that is what the patent is really about; the fact that the patent would be infringed because (and only because) that active ingredient is used in a combination of active ingredients does not mean that the patent is really about the combination or really about any other active ingredient in the combination. Thus in *Medeva*, the patent was not really about any of the active ingredients other than A and B (to use the summary of the facts set out at paragraph 13 above).

56. In relation to a claim to a product which "comprises" the active ingredient, this approach produces the same answer. A combination which includes the active ingredient would then fall within the definition of the claim. However, what the patent is really about is the active ingredient; the patent is no more really about the other active ingredients or indeed the combination than it is in the case where the claim is not enlarged by the use of a word such as "comprises". And likewise, where the patent is for a combination of, say, two expressly identified active ingredients but not for each active ingredient taken separately, the patent is really about the combination and not about each active ingredient. That is similar to the position in *Yeda* where the combination of cetuximab and irinotecan was protected (within the meaning of Article 3(a)) but cetuximab, taken by itself, was not.

57. Mr Tappin's appeal to what a patent is really about has considerable attraction. Whether it can stand as an explanation of what the Court actually said is a different matter. A closer examination is necessary.

58. He attaches great importance to [31] and [32]. He submits that they show that the rules for determining what is "protected by a basic patent" for the purposes of Article 3(a) are those relating to the extent of the invention covered by the patent, that is to say section 125 or, for European patents, Article 69 EPC and the Protocol. He thus perceives an alignment by the Court of its analysis under Article 3(a) with its analysis under Article 69 EPC. As if to underline that approach, the Court in [33] effectively

reiterates that recourse is not to be had to the infringement test and so, as is pointed out in [37], infringement is not the crucial factor. Those paragraphs, along with [34] and [35] are all part of the emphasis which the Court is placing on the importance of the claims and what falls within them in contrast with, for instance, the potential for infringement. This, he says, is all readily understandable with *Medeva* in mind where, to take the explanation given above, ingredients X, Y and Z have nothing at all to do with the patent claims.

59. As to [36], it was, indeed, common ground before the Court (and remains common ground) that tabalumab is not expressly named in the claims of the patent. Mr Waugh says that it was also common ground before the Court that tabalumab was not otherwise specified in the description or specification. Mr Tappin accepts that it is not possible to find a description of tabalumab in the Patent in the sense that the sequence for tabalumab cannot be found anywhere in it, whether in the description or the claims. In that sense, it was common ground that tabalumab was not specified in the Patent. But it was not common ground that tabalumab was not specified in the sense in which that word was being used in *Medeva*. That, if I may say so, is obvious since, had it been common ground, the reference to the Court would have been unnecessary and the Court could have delivered a very different, and even shorter, judgment. The words "identified as such" do not, he submits, add anything. In agreement with that, I would say that, if anything, it only goes to underline the extent of the common ground as Mr Tappin has identified, namely that there is nothing in the Patent which can be pointed to enable the reader to identify tabalumab in contradistinction to any other antibody binding to Neutrokine-α.

60. In [38], the Court refers to the case law previously cited at [34]. It reiterates that an active ingredient which is not identified in the claims of a basic patent (again the emphasis is on the claims) is not protected for the purposes of Article 3(a) and, importantly, this is said to be so whether the active ingredient is identified by a structural or functional definition. In this paragraph, the Court uses the word "identified" which, as already explained, means the same as "specified" in *Medeva* but, as it seems to me, means something different from "specified" in [36] of the Judgment. [38] does not, of course, stand in isolation: it follows on from, and is to be read together with, what is said in [37], which underlines that issues of infringement are not crucial in the determination of whether the active ingredient is protected by the patent. And so, it seems to me, [36] to [38] are saying no more than that tabalumab is not <u>expressly</u> identified in the claims of the Patent, that questions of infringement are not relevant and that the active ingredient must be "identified" as much in the case of a functional definition as in the case of a structural definition.

61. Unfortunately, the Court does not, in [38], say what it means by "identified" other than by reference to the case law just referred to; nor does it do so anywhere else in the Judgment save, perhaps, in [39] to which I will come in due course. In *Medeva*, the Court used the word "specified" to identify what is protected. It is a word which is entirely apposite in the context of a combination. But even in combination cases, its meaning will not, in all cases, be clear.

62. As already pointed out, the position after *Medeva* was that the infringement test had been rejected in combination cases (and has clearly now been rejected in other cases). The contest in *Medeva* was between an infringement test and a scope of subject matter/extent of protection test. The Court in *Medeva* did not give guidance about the

correct criteria to use in assessing that latter test. Thus in the Court of Appeal, the Chancellor was able to say that, on any view, the active ingredients relating to the vaccines were excluded; but he could go no further than give a range of possible meanings to "specified". And so, in the case of a single active ingredient, as much as in relation to combinations, it was entirely unclear after *Medeva* where the line was to be drawn.

63. It is disappointing, therefore, to find that the Judgment does not give express guidance about what it meant by "specified" in *Medeva* or "identified" in the subsequent cases mentioned above when it must have been obvious from the reference that this was what I was seeking. Instead, at [38] it simply states that an active ingredient must be "identified" in order to be protected by the basic patent.

64. There may be different explanations for this. One is that the Court thought that the only guidance which was being sought related to the sufficiency of a functional definition as a matter of principle. I find this explanation difficult to believe given the actual questions referred.

65. Another, more likely, explanation is that the Court considered the guidance in *Medeva* to be sufficient once it had identified, in [32], the applicable rules for determining what is protected. In other words, it perceived the difficulties arising out of the use of the word "specified" or "identified" as an issue concerning which rules were to apply in ascertaining what is specified or identified. Once those rules are identified, it is to be left to the national courts to ascertain the extent of the invention and the scope of the claims. That will give an answer to whether the basic patent protects a product. If the product falls within the claims, it will be protected within Article 3(a). This, however, has to be made subject to one proviso to which I turn.

66. The proviso relates to products which are combinations of active ingredients and is necessary to reflect the *Medeva* approach where the claims contain some general word or words extending their extent beyond the principal scope of the claims, typically by the use of a word such as "comprises". In the absence of such an extending word, the claims have a focused scope and the question is simply whether the product falls within the scope of the claims. In the language of *Medeva,* the question is whether the product (ie the combination of active ingredients) is "specified" in the claims, a question which is answered by a close examination of the claims. If general words are included, the position is different. The product does not fall within the focus of the claims and is not within its scope apart from the general words. In such a case, the product is not "specified" any more than it is "specified" where the general words are absent.

67. Some further help is to be obtained from [39]. This paragraph gives a clear answer to the question whether a functional definition can, in principle, be sufficient to bring an active ingredient within the protection of the basic patent. The answer is that it can, provided that the claims relate implicitly but necessarily and specifically to the active ingredient.

68. It is to be noted that the Court has not earlier in the Judgment mentioned the concept of "relating" to the active ingredient or used the phrase (or anything remotely resembling it) "implicitly but necessarily and specifically". It seems to me that what the Court is doing here is to align (i) what it is for an active ingredient to be

"identified" in the basic patent (in the case of a functional definition) with (ii) what it is for the basic patent to "relate, implicitly but necessarily and specifically to the active ingredient in question". The Court might have stopped at [39] before the words "on condition". That, however, would have given no guidance at all about what it meant for an active ingredient to be "identified" in the claims of the basic patent. Whatever it thought about the adequacy of the guidance which it had (or had not) already given in relation to structural claims in *Medeva* and subsequent cases, the Court clearly sought to give some guidance in relation to functional claims which were, after all, the subject-matter of the reference and in relation to which specific questions had been asked. My conclusion, therefore, is that the Court was saying that an active ingredient is "identified" so as to fall within the protection of a basic patent if the active ingredient is within the claims of the basic patent provided the claims relate, implicitly but necessarily and specifically, to the active ingredients. Those words reflect, in the context of a functional definition, no more and no less than the word "specified" in *Medeva* and "identified" in subsequent cases.

69. The words "implicitly but necessarily and specifically" are required as a qualification. Without them, it might be thought that the claims would "relate" to any product which included the active ingredient. Consider an example where the facts are the same as those in *Medeva* as described in paragraph 13 above but where the claims to A and B are purely functional claims. It might be said that the claims (to A and B) "relate" to the product comprising A, B, X, Y and Z. But clearly, following *Medeva*, that product is not "protected by a basic patent in force" for the purposes of Article 3(a). This is made clear by the qualification that the claims must relate "implicitly but necessarily and specifically" to the active ingredient(s) in question. The patent, in this example, would not so relate (or indeed relate at all) to X, Y and Z or to the combination of A, B, X, Y and Z and so would not form the basis of an SPC in relation to the product.

70. Lilly's approach is in effect that the word "identified" in [38] of the Judgment means that the patent must contain a description or definition of the active ingredient in question which provides some sort of detail from which it can be ascertained. That in turn means that the words "relate, implicitly but necessarily and specifically to the active ingredient in question" require the same sort of definitional detail. Mr Tappin has suggested that what Lilly requires is what he calls an individualised description. Mr Waugh takes exception to that, at least if what is meant is that an entire amino acid sequence of the active ingredient has to be found. I do not consider that either Mr Waugh's approach or what Mr Tappin says about the need, on Lilly's argument, for an individualised description adequately reflects what the Court is saying. On the one hand, an individualised description of that sort cannot be what the Court had in mind and Mr Waugh does not suggest that it is: it has never been Lilly's case that an individualised description in that sense is required. On the other hand, for reasons given elsewhere in this judgment, the focus of what the Court is saying is on the claims and it is not correct to read the Court as requiring a more detailed definition to be found in the description of the invention, if it is not be found in the claims themselves. In my judgment, the correct reading of [39] of the Judgment and the answer the Court gives, demand an application of the relevant rules (Article 69 or section 125) to ascertain the extent of the invention and what the claims relate to. If the active ingredient in question is covered by the claims, the active ingredient is,

subject to the proviso explained at paragraph 66 above, protected for the purposes of Article 3(a).

71. The same treatment thus applies to a structural claim and to a functional claim. In *Medeva*, the active ingredients A and B fell within the claims of the patent. But the combination of A, B, X, Y and Z was not protected by the patent; and this would have been so even if the claims had been for a product which "comprises" A or for one which "comprises" A together with some other active ingredient. It is only A and B which are "specified" or "identified". Similarly in the case of a functional claim. If a particular active ingredient, C, is subsequently isolated and identified, and falls within the claims properly construed, the claim "relates, implicitly but necessarily and specifically" to C. But just as the combination in *Medeva* was not protected, so too a combination of C and other active ingredients would not be protected even if the claim was to a product which "comprises" C.

72. The Court states that, in principle, a functional definition can be sufficient. It is not likely that the Court, in saying that, intended the test to be so high that it would be impossible or virtually impossible in practice for an active ingredient ever to be sufficiently indicated by a functional definition alone. If it is necessary to go beyond the claims (interpreted in the light of the description as required by Article 69) and to find in the description something which identifies the active ingredient in some detailed way, I find it hard to imagine what that "something" could be other than a structural description and hard to imagine how a particular antibody within a class of antibodies which are claimed by the claims could be identified individually by a purely functional definition. The Court surely cannot have been saying that functional definitions in the claims are good enough in principle but only if the description contains some sort of structural definition.

73. So, what would be required, if Mr Tappin's submissions are to be rejected, for an active ingredient to be identified and where would that identification have to be found? As to the second of those questions, the answer could only be in the description since, on the hypothesis that Mr Tappin is wrong, the active ingredient is not, in the present case, found in the claims. I see no warrant for reading the Judgment as requiring the active ingredient to be specified in the description and I see a submission to that effect as no more than an assertion of the conclusion. The clear focus of the Judgment is on the claims, interpreted of course in accordance with the description as required by Article 69. I reject submissions to the contrary.

74. As to the first question, it cannot be that the Court is requiring an individualised description of the particular active ingredient under which it is necessary to write down a very detailed description going far beyond just the CDRs; and it has never been Lilly's case that that is required. But if something less is sufficient, what is it? There is no firm foundation for adopting any particular definition as sufficient and, certainly, the Court gives no guidance at all about that. In particular, I can see no reason for saying that disclosure of the CDRs, rather than some other part of the molecule, for instance the framework residues, is sufficient. In any case, we would still be left with a structural definition which is contrary to the Court's decision that a functional definition is, in principle, sufficient.

75. I have dealt, in the above discussion, with some of the arguments which are raised in Mr Waugh's and Mr Mitcheson's skeleton argument and in Mr Waugh's oral

submissions. In the skeleton, it is said that Lilly has three basic answers to HGS's submission that it is enough to bring the product within the protection of Article 3(a) if the patent contains a functional claim wide enough to cover the antibody in question:

i) It is not what the Judgment says.

ii) If it were that simple, the Judgment would have said so.

iii) Such an approach is flatly contradictory to the approach in *Medeva* and the surrounding case law which is applied in the Judgment. The only way to reconcile those cases with the Judgment is to hold that the requirement that the claims "relate, implicitly but necessarily and specifically, to the active ingredient in question" means that they relate to the product sufficiently identified in the specification of the Patent (in the light of which the claims are to be construed).

76. Let me get argument ii) out of the way immediately. One thing which is clear, unfortunately, is that the Judgment does not give the guidance which I had hoped for and, in particular, it does not enlarge on what it meant by "specified" or "identified" in the earlier cases nor does it explain what it meant by "relates, implicitly but necessarily and specifically". Mr Waugh submits that, if matters were as simple as HGS suggest, the Court would have said so. But that line of argument cuts both ways: it can also be said that, if the correct approach is that for which Mr Waugh contends, the Court could, again, easily have said so. I do not find any significant assistance in submissions about how the Court might have expressed itself differently. In any case, it will be apparent from what I have said above, that I do not think that the approach which Mr Waugh attributes to HGS is correct. An approach which simply looks at what is covered by the claims in the sense of establishing whether a product, as a matter of construction, falls within the claims is not in all cases correct. This is because of the proviso which I have mentioned at paragraph 66 above. In the context of a product which consists of a single active ingredient, it may be that the Judgment could have taken the simple form which Mr Waugh suggests. But the Judgment was speaking in more general terms. The Judgment does give some guidance, as I have mentioned, in [31] and [32] and is to the effect that the rules for determining whether a product is protected by a basic patent are to be found in Article 69; that guidance applies as much to a product containing more than one active ingredient as to a product containing a single active ingredient and it applies to cases where the patent provides a functional definition as well as to cases where it provides a structural definition. It is not at all obvious that the Court would have expressed itself differently if it had been intending to articulate the approach which I favour, namely that for which Mr Tappin contends but subject to the proviso which I have mentioned.

77. Further, in saying what it did in [32] (identifying section 125 and Article 69 as the relevant provisions), it did not adopt (and, I think, can be seen as impliedly rejecting) Lilly's submission, in reliance on Articles 83 and 84, that the criteria for deciding whether a product is protected are that the product is sufficiently identified and enabled by the description and the claims so as to be capable of being used as an active ingredient in a medicinal product and thereby the subject of an MA.

78. Arguments i) and iii) fall to be treated together. Mr Waugh submits that it is plain that in [38] the Court is rejecting the idea that a merely functional definition without identification of the product is enough. That, of course, depends on what is meant by identification of the product. And whilst tabalumab is not expressly mentioned and nor is it specified in the sense that the sequence for tabalumab cannot be found anywhere in it, the Court was not saying, for reasons which I have already given, that tabalumab was not "specified" or "identified" in the sense in which those words were being used in *Medeva* and the other cases.

79. Mr Waugh submits that from the whole of [39] to [44], the Court is seeking to apply its own test for a 'functional language' claim to conclude that the test has not been met by the Patent. The test he describes derives from the words in [44] "in the light of the description of the invention.... the claims relate *etc*". And it is those words which he relies on to justify the conclusion that what the claims relate to must be something disclosed in the description. "It cannot mean" he says "just 'relate' to an antibody in an abstract sense". In identifying the test by reference to those words, I fear Mr Waugh may mislead himself to some extent. The actual words used by the Court are "that it is possible to reach the conclusion on the basis of those claims interpreted inter alia in the light of the description of the invention, as required by Article 69.... that the claims relate....". It is clear that the focus is the claims and by relying on the words which he does, Mr Waugh misses that focus. The claims must, of course, be interpreted in accordance with Article 69 and therefore in the light of the description, since that is what Article 69 requires. But I see no warrant for the suggestion that something must be found in the description which provides a more detailed definition of any particular antibody. I am not sure quite what Mr Waugh means when he uses the word "abstract" other than that the antibody is not named or specified (in the sense I have just described) in the patent in question.

80. His argument places great reliance on [43]. He says that the way matters are put there reflects Lilly's submissions to the Court in relation to the Specification Issue. I do not consider that it is appropriate to construe the Judgment against those submissions which are not referred to in the Judgment and which a reader of the Judgment (other than one involved in the proceedings) would not know about. He also relies on the opening words of [44], submitting that [42] and [43], as much as what had gone before, form part of the reasoning leading to the answer given. I have already addressed in considerable detail how I see [42] and [43] are to be interpreted. I do not accept that they are to be read in the way which Mr Waugh submits they should be read; and in particular, I do not agree with his submission that the first sentence of [43] is referring expressly to an acknowledged failure by HGS to identify tabalumab specifically in the sense that the test under Article 3(a) requires. Instead, the Court is reflecting what it said in [36] about the common ground between the parties which I have already discussed. The Court is not, I consider, adding to the test which it has set out earlier in the Judgment about how to assess whether to grant an SPC. Rather, it is explaining why, if the test is not satisfied, the refusal of the SPC can be further justified.

81. Mr Waugh submits that in reality, HGS's approach is indistinguishable from adoption of the infringement test which has been clearly rejected by the Court. He can pray in aid what the Chancellor said in *Medeva* in the Court of Appeal, as to which see paragraph 26 above, where he said that there must be some wording indicating that

the other elements are included in the claims otherwise the Court of Justice would be imposing the infringement test. I do not agree with that submission. The test which Mr Tappin presents will give the same result as an infringement test in many cases; but that is certainly not so in all cases (as the need for the proviso which I have identified demonstrates) and the two are conceptually distinct.

Conclusions

82. There is no doubt that tabalumab is an antibody which binds to Neutrokine-α or the extracellular domain of Neutrokine-α. There is also no doubt – at least it is accepted by Lilly for the purposes of the present application – that tabalumab falls within claim 13 properly interpreted. It is not simply that sales of tabalumab would infringe claim 13. In my judgment, claim 13 "relates" to tabalumab and does so "implicitly but necessarily and specifically". Accordingly, Lilly's application for a declaration fails.

83. If I am wrong in the approach which I have taken and something more detailed is required by way of definition of a product in the patent if it is to be protected for the purposes of Article 3(a), my error would, I think most likely, be in my approach to [42] and [43] of the Judgment: the fact that a patent holder had incurred no expenditure on further research would then be an important factor to be taken into account (in a way which I do not understand) in deciding whether the product is protected by the patent. In contrast, in a case where the patent holder had himself incurred expenditure on developing the product and obtaining an MA for it, the reasoning of the Court would not apply and there is nothing in [43] which would point to an SPC being refused. It is therefore critical to know, in the present case, what, if any, research HGS has undertaken, and what expenditure it has incurred which might have been of benefit to Lilly in developing tabalumab – and a further reference in the light of the findings of fact might be necessary – before it was possible to rule whether tabalumab is adequately defined so as to be protected under Article 3(a) by reference to the Patent. I would refuse to make the declaration sought in these circumstances.

84. Accordingly, Lilly's claim for a declaration is dismissed.